instrument at a predetermined power.

12. The method of Claim 11 wherein said transverse thickness is within a range of about ten to about one hundred microns.

13. A method for detecting the presence or absence of circulating target abnormal nucleated cells in an anticoagulated whole blood sample, said method comprising the steps of:

a) providing a transparent tube having a bore which contains an axially elongated insert, said tube and insert combining to form a well-defined zone in the tube which well-defined zone has a transverse thickness that is at least about ten microns;

b) combining the blood sample with one or more epitope-specific labeling agents so as to differentiate any abnormal target nucleated cells in the blood sample;

c) combining the blood sample with a colorant which is operable to clarify cell morphology in all nucleated cells in the blood sample;

d) placing the blood sample in the tube and centrifuging the blood sample in the tube so as to cause any abnormal nucleated cells present in the blood sample to gravitate by density into said well-defined zone in the tube;

e) examining the well-defined zone under magnification and enumerating any differentiated cells found in situ in the well-defined zone in the tube;

f) examining under magnification the cell morphology of any differentiated cells in situ in the well-defined zone in the tube;

g) said combining steps being performed either before or after the blood sample is placed in the tube; and

h) said enumerating and examining steps being performed in no particular order.

14. A method for detecting the presence or absence of circulating target nucleated cells in a centrifuged sample of anticoagulated whole blood contained in a tube which tube also contains a generally cylindrical insert that forms a well-defined annular zone in the tube, said blood sample having been combined with one or more epitope-specific labeling agents that are operative to produce a characteristic signal result on target nucleated cells, which result can include no signal at all, and which result is defined by the presence or absence of one or more epitopes on the target nucleated cells, and said blood sample having also been combined with a colorant which is

Claims

1. A method for detecting the presence or absence of circulating target abnormal nucleated cells in an anticoagulated whole blood sample, said method comprising the steps of:

a) providing a transparent tube having a bore containing a generally cylindrical insert, said tube and insert combining to form a well-defined zone in the tube;

b) combining the blood sample with one or more epitope-specific labeling agents so as to differentiate any abnormal target nucleated cells in the blood sample;

c) combining the blood sample with a colorant which is operable to clarify cell morphology in all nucleated cells in the blood sample;

d) placing the blood sample in the tube and centrifuging the blood sample in the tube so as to cause any abnormal nucleated cells present in the blood sample to gravitate by density into said well-defined zone in the tube;

e) enumerating any differentiated cells found in situ in the well-defined zone in the tube;

f) examining the cell morphology of any differentiated cells in situ in the well-defined zone in the tube;

g) said combining steps being performed either before or after the blood sample is placed in the tube; and

h) said enumerating and examining steps being performed in no particular order.

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2. A method for detecting the presence or absence of circulating target abnormal nucleated cells in a centrifuged sample of anticoagulated whole blood contained in a tube which tube also contains a generally cylindrical insert which forms a well-defined annular zone in the tube, said blood sample having been combined with one or more labeling agents that are specific to one or more epitopes on the abnormal target nucleated cells, and said blood sample having also been combined with a colorant which is operable to clarify cell morphology in all nucleated cells in the blood sample, said method comprising the steps of identifying a percentage of all labeled cells which are disposed in said well-defined annular zone in situ in the tube, and examining the cell morphology of any such identified cells in situ in the tube so as to determine whether any such identified cells display abnormal cell morphology.

3. A method for enumerating circulating epithelial cells in a centrifuged sample of anticoagulated whole blood which sample is contained in a transparent tube, which tube also contains a generally cylindrical insert, and which blood sample has been combined with at least one labeling agent that is specific to at least one epithelial cell epitope, and which blood sample has also been combined with a colorant that clarifies nucleated cell morphology, said method comprising the steps of examining a well-defined zone in the tube wherein platelets in the blood sample have gravitated during centrifugation and enumerating any labeled epithelial cells having abnormal morphology in situ in the tube which cells have gravitated by density during centrifugation into said well-defined zone in the tube.

4. A method for differentiating cancer cells from hematologic progenitor cells and from other nucleated cells in a sample of anticoagulated whole blood, said method comprising the steps of:

a) providing a sample of anticoagulated whole blood containing epitopic cell labeling materials which are operable to differentiate cancer cells and hematologic progenitor cells from each other and from other nucleated cells in the sample, said sample being contained in a transparent tube which also contains an insert that is operable to form a well-defined zone in the tube;

b) centrifuging the sample of blood in the tube so as to gravimetrically separate the blood sample into its constituent components and so as to settle by density any nucleated cells which are not conventional blood cells in the sample in said well-defined zone in the tube; and

c) examining said well-defined zone in the tube in order to determine whether any differentiated nucleated cells are present in said well-defined zone in the tube.

5. A method for enumerating cancer cells and/or hematologic progenitor cells in a sample of anticoagulated whole blood, said method comprising the steps of:

a) providing a sample of anticoagulated whole blood containing epitopic cell labeling materials which are operable to differentiate cancer cells and hematologic progenitor cells from each other and from other nucleated cells in the sample, said sample being contained in a transparent tube which also contains an insert that is operable to form a well-defined zone in the tube;

b) centrifuging the sample of blood in the tube so as to gravimetrically separate the blood sample into its constituent components and so as to settle any nucleated cells in the sample in said well-defined zone in the tube by density;
c) examining said well-defined zone in the tube in order to determine whether any differentiated nucleated cells are present in said well-defined zone in the tube; and
d) enumerating any cancer cells and/or hematologic progenitor cells which are found to be present in said well-defined zone in the tube.

6. A method for analyzing a sample of anticoagulated whole blood in order to determine the presence or absence of cancer cells and/or hematologic progenitor cells in the sample, said method comprising the steps of:
a) providing a sample of anticoagulated whole blood containing epitopic cell labeling materials which are operable to differentiate cancer cells and hematologic progenitor cells from each other and from other nucleated cells in the sample and containing a cell morphology-clarifying stain, said sample being contained in a transparent tube which also contains an insert that is operable to form a well-defined zone in the tube;
b) centrifuging the sample of blood in the tube so as to gravimetrically separate the blood sample into its constituent components and so as to deposit by density any nucleated cells in the sample, which are not blood cells, in said well-defined zone in the tube; and
c) examining said well-defined zone in the tube in order to determine whether any differentiated nucleated cells are present in said well-defined zone in the tube.

7. A method of identifying circulating epithelial cells in a centrifuged sample of anticoagulated whole blood which sample is contained in a transparent tube, which tube also contains an axially elongated insert, and which blood sample has been combined with at least one labeling agent that is specific to at least one epithelial cell epitope, said method comprising the steps of examining a well-defined zone in the tube wherein platelets in the blood sample have gravitated during centrifugation and identifying any labeled epithelial cells in situ in the tube which labeled cells have gravitated by density into said well-defined zone in the tube during centrifugation of the sample in the tube.

8. A method for morphometrically analyzing a centrifuged anticoagulated blood

sample for abnormal circulating epithelial cells, which sample is contained in a transparent tube, which tube also contains a generally cylindrical insert, and which blood sample has been combined with a stain for clarifying cellular morphology of epithelial cells, said method comprising the steps of: examining a well-defined zone in the tube wherein platelets in the blood sample have gravitated during centrifugation; and morphometrically examining any epithelial cells in situ in the tube, which epithelial cells have gravitated by density into said well-defined zone in the tube during centrifugation of the sample in the tube so as to determine whether any such cells possess abnormal morphology.

9. A method for detecting the presence or absence of circulating target abnormal nucleated cells in an anticoagulated whole blood sample, said method comprising the steps of:

a) providing a transparent tube having a bore containing an axially elongated insert, said tube and insert combining to form a well-defined zone in the tube;

b) combining the blood sample with one or more epitope-specific labeling agents so as to differentially highlight any abnormal target nucleated cells in the blood sample;

c) combining the blood sample with a colorant which is operable to clarify cell morphology in all nucleated cells in the blood sample;

d) placing the blood sample in the tube and centrifuging the blood sample in the tube so as to cause any abnormal nucleated cells present in the blood sample to gravitate by density into said well-defined zone in the tube;

e) enumerating any labeled cells found in situ in the well-defined zone in the tube;

f) examining the cell morphology of any labeled cells in situ in the well-defined zone in the tube;

g) said combining steps being performed either before or after the blood sample is placed in the tube; and

h) said enumerating and examining steps being performed in no particular order.

10. The method of Claim 9 wherein said enumerating and examining steps are performed with a microscopical instrument.

11. The method of Claim 10 wherein said well-defined zone has a transverse thickness which is essentially equal to a focal operating range of the microscopical

operable to clarify cell morphology in all nucleated cells in the blood sample, said method comprising the steps of identifying by cell morphology all nucleated cells that may be target cells and which are disposed in said well-defined annular zone, and further characterizing all identified nucleated cells as target cells or non-target cells epitopically, said identifying and characterizing steps being performed in situ in the tube.

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